UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Docket No. 20-72091
Consolidated with Docket No. 20-72376

NEIGHBORS FOR ENVIRONMENTAL JUSTICE et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY et al.,

Respondents,

HALOGENATED SOLVENTS INDUSTRY ALLIANCE et al.,

Respondents-Intervenors.

On Petition for Review of Final Order of the U.S. Environmental Protection Agency

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OPENING BRIEF OF PETITIONERS NEIGHBORS FOR ENVIRONMENTAL JUSTICE; NEW JERSEY WORK ENVIRONMENT COUNCIL; SIERRA CLUB; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO; and NATURAL RESOURCES DEFENSE COUNCIL

Dated: January 25, 2021 *Counsel listed on the next page*

s/Selena Kyle
SELENA KYLE
Natural Resources Defense Council
1600 N. Wacker Dr., Ste. 1600
Chicago, IL 60606
T: 818.720.5953
skyle@nrdc.org

ROBERT GUSTAFSON
Natural Resources Defense Council
40 W. 20th St., Fl. 11
T: 847.977.8339
rgustafson@nrdc.org

Attorneys for Petitioners Neighbors for Environmental Justice and Natural Resources Defense Council

s/Randy S. Rabinowitz
RANDY S. RABINOWITZ
Occupational Safety & Health Law Project
P.O. Box 3769
Washington, DC 20027
T: 202.256.4080
randy@oshlaw.org

Attorney for Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO

s/Jonathan Kalmuss-Katz
JONATHAN KALMUSS-KATZ
Earthjustice
48 Wall St., 15th Fl.
New York, NY 10005
T: 212.845.7376
jkalmusskatz@earthjustice.org

Attorney for Petitioners Neighbors for Environmental Justice, New Jersey Work Environment Council, and Sierra Club

CORPORATE DISCLOSURE STATEMENT

Petitioners Neighbors for Environmental Justice, New Jersey Work Environment Council (NJWEC), Sierra Club, and Natural Resources Defense Council (NRDC) are nonprofit organizations with no parent companies, subsidiaries, or affiliates that have issued shares to the public in the United States or abroad. Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO (United Steelworkers) is a labor organization, and likewise has no parent companies, subsidiaries, or affiliates that have issued shares to the public in the United States or abroad. No publicly held corporation owns 10% or more of stock in Neighbors for Environmental Justice, NJWEC, Sierra Club, NRDC, or United Steelworkers.

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TABLE OF ABBREVIATIONS

APA	Administrative Procedure Act
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act
IRIS	Integrated Risk Information System
IUR	Inhalation unit risk
NIOSH	National Institute for Occupational Safety and Health
NRDC	Petitioner Natural Resources Defense Council
NJWEC	Petitioner New Jersey Work Environment Council
OSHA	U.S. Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act
PEL	Permissible exposure limit
PF	Protection factor
PPE	Personal protective equipment
SDS	Safety data sheet
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
Science Committee	EPA's Science Advisory Committee on Chemicals
United Steelworkers	Petitioner United Steel, Paper, and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO
Risk Evaluation	EPA's final Risk Evaluation for methylene chloride (issued June 2020)

PRELIMINARY STATEMENT

Congress enacted the Toxic Substances Control Act (TSCA) to protect the public from the risks of toxic chemicals like methylene chloride, which causes cancer, other serious health effects, and—in higher doses—sudden death. Congress amended TSCA in 2016 to require EPA to prepare comprehensive evaluations of chemicals' threats to human health and the environment and to give special consideration to the most exposed and vulnerable groups. Where a risk evaluation shows that a chemical poses an unreasonable risk to health or the environment, TSCA requires EPA to eliminate the unreasonable risk through regulation.

EPA's final risk evaluation for methylene chloride (Risk Evaluation), issued in June 2020, is a far cry from the comprehensive study Congress mandated. EPA ignores releases of the chemical into air, water, and soil, and thus fails to account for the resulting human exposures and risks to human health. EPA does not account adequately for two subpopulations that are among the most exposed and vulnerable: neighbors of industrial and commercial sites that release methylene chloride into the air, and people whose genetics make them especially likely to develop cancer after exposure. EPA also grossly understates risks to workers in high-exposure settings like manufacturing plants, by assuming—contrary to OSHA regulations, substantial evidence in the record, and the best available science on occupational exposure assessment—that workers will be protected by bulky and

expensive supplied-air respirators and chemical-resistant gloves. EPA also understates risks by failing to combine individuals' inhalation exposures with their simultaneous dermal exposures, and by failing to account for the fact that many individuals are exposed in more than one way (for example, while at work, while commuting, and while using consumer products at home).

These errors and omissions have serious consequences. They mean that EPA will not take regulatory action under TSCA to protect many of the people who are *most* likely to be exposed at levels that present an unreasonable risk. To ensure that these people receive the protections Congress intended, the Court should vacate EPA's findings of no unreasonable risk, remand, and order EPA to revise the Risk Evaluation to account for the full range of human exposures to methylene chloride and the consequences of those exposures.

STATEMENT OF JURISDICTION

EPA prepares risk evaluations pursuant to TSCA section 6. *See* 15 U.S.C. § 2605(b). Section 6(i)(1) provides that "a determination by [EPA] … that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action." *Id.* § 2605(i)(1). Section 5.4.1 of the Risk Evaluation "constitutes the order required under TSCA section 6(i)(1)." Pet'r. Excerpts of Record Vol. 1 (1-

NFEJ_ER)[1] 199. It announces EPA's determination "that the following conditions of use of methylene chloride do not present an unreasonable risk of injury to health or the environment": (1) domestic manufacture; (2) processing: as a reactant; (3) processing: recycling; (4) distribution in commerce; (5) industrial and commercial use as a laboratory chemical; and (6) disposal.[2] 1-NFEJ_ER-198–201.

"[A]ny person" may petition for review of an order issued under section 6(i)(1) within 60 days of issuance, in any appellate circuit "in which such person resides." 15 U.S.C. § 2618(a)(1)(A). EPA notified the public of its issuance of the Risk Evaluation on June 24, 2020, *see* 85 Fed. Reg. 37,942, and Petitioners petitioned for review in this Circuit, where Petitioner Sierra Club resides, on July 16. Pet. for Review; Pet'r. Addendum (NFEJ_PA) 35 (Isherwood ¶ 3).[3]

STATEMENT OF ISSUES

1. TSCA says EPA "shall conduct risk evaluations … to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment … under the conditions of use." 15 U.S.C. § 2605(b)(4)(A).

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[1] Volume 1 contains Risk Evaluation excerpts, and Volume 2 (2-NFEJ_ER) other excerpts. Semicolons denote jumps from one excerpted document to another.

[2] Petitioners refer to these conditions as the "six occupational conditions of use" or "six conditions of use." EPA determined that forty-seven other "conditions of use" present an unreasonable risk. 1-NFEJ_ER-199–201. EPA made no finding that the *chemical substance* methylene chloride does not present an unreasonable risk. 1-NFEJ_ER-198–201; *see also infra* n.43.

[3] The Addendum contains Petitioners' declarations in support of standing.

"Conditions of use" are "the circumstances … under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). Did EPA violate TSCA and act arbitrarily and without substantial evidence when it excluded releases of methylene chloride into air, water, and soil and associated exposures and risks of injury to human health from the Risk Evaluation, even though these environmental releases and exposures are caused by the chemical's "conditions of use"?

2. TSCA requires risk evaluations to "determine whether a chemical substance presents an unreasonable risk … including an unreasonable risk to a potentially exposed or susceptible subpopulation," *id.* § 2605(b)(4)(A), and to use "the best available science," *id.* § 2625(h). A potentially exposed or susceptible subpopulation is "a group of individuals within the general population … who, due to either greater susceptibility or greater exposure, may be at greater risk" of adverse health effects after exposure. *Id.* § 2602(12). Did EPA violate TSCA and act arbitrarily and without substantial evidence when it failed to identify people who live in communities neighboring industrial and commercial emitters of methylene chloride as a "potentially exposed" subpopulation, and failed to determine whether the chemical poses an unreasonable risk to that group, or to another subpopulation EPA identified, whose genetics make them especially susceptible to developing cancer after being exposed?

3. TSCA, consistent with longstanding occupational hygiene practice and the best available science, permits EPA to consider risk-management tools such as personal protective equipment (PPE) use only after it completes a risk evaluation for a chemical. Did EPA violate TSCA and act arbitrarily and without substantial evidence when it assumed, contrary to record evidence, that workers who are exposed to unsafe levels of methylene chloride will be provided with, trained on, and protected by respirators and other forms of PPE?

4. EPA's TSCA regulations and federal administrative law require EPA to respond to comments from its Science Advisory Committee on Chemicals and from the public. Was it lawful for EPA to refuse to answer Committee and public comments asking it to explain why it used an estimate of methylene chloride's carcinogenicity that is almost thirty times less protective than the figure OSHA used in its occupational risk assessment for the chemical, even though OSHA's estimate is based on the same underlying research data?

5. TSCA requires EPA to determine whether "the manufacture, processing, distribution in commerce, use, or disposal of [methylene chloride], or … *any combination of such activities*, presents an unreasonable risk," 15 U.S.C. § 2605(a) (emphasis added), and to "integrate and assess available information on hazards and exposures for the conditions of use of [methylene chloride], including information that is relevant to specific risks of injury to health," *id.*

§ 2605(b)(4)(F)(i). Did EPA violate TSCA and act arbitrarily and without substantial evidence when it based its risk determinations on figures that do not account for individuals' simultaneous inhalation and dermal exposures, and for combined exposures from more than one condition of use?

STATUTORY ADDENDUM

Petitioners attach a separate Statutory Addendum. *See* 9th Cir. R. 28-2.7.

STATEMENT OF THE CASE

I. Methylene chloride's dangers to health and the environment

Methylene chloride causes cancer and other serious health effects. 1-NFEJ_ER-80–91 (evidence that exposure is associated with liver, breast, and other cancers); 1-NFEJ_ER-56–79 (evidence of harms to the liver, immune, and nervous systems, as well as reproductive and developmental effects). At high doses the chemical is immediately lethal: it "can starve the heart of oxygen and prompt an attack" and cause people to stop breathing because "the respiratory centers of their brains switch off." 82 Fed. Reg. 7464, 7482 (Jan. 19, 2017) (internal quotation marks omitted). Methylene chloride released into the environment also contributes to ozone depletion and increases the risk of health problems associated with exposure to ultraviolet radiation, such as skin cancer and cataracts. 2-NFEJ_ER-276–79; 2-NFEJ_ER-293 & n.20.

People can be exposed to methylene chloride in many ways, including by working in facilities that manufacture, use, recycle, and/or dispose of the chemical; by using consumer products that contain the chemical, such as paints, glues, and automotive care products; and through environmental pollution. 1-NFEJ_ER-98–201. Large industrial facilities in the United States release more than two and a half million pounds of methylene chloride into the environment each year.[4] People who live and work nearby are especially exposed to and threatened by those releases.[5]

II. TSCA's risk-evaluation and risk-management requirements for toxic chemicals

A. Congress's enactment of TSCA

Congress enacted TSCA to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1

[4] *See* 2-NFEJ_ER-301 (summarizing Toxics Release Inventory (TRI) data for 2015); NFEJ_PA-56–59 (¶¶ 2-4), 64 (compiling and summarizing TRI data reported to EPA for more recent years); *Safer Chems., Healthy Families v. EPA*, 943 F.3d 397, 420 n. 13 (9th Cir. 2019) ("[A] court may take judicial notice of matters of public record," including information published on EPA's website. (internal citation marks and quotations omitted)). These figures understate actual releases: not all facilities are subject to TRI requirements, some may underreport, and only releases of more than 10,000 pounds per year must be reported. *See* 42 U.S.C. § 11023(b), (f); 40 C.F.R. § 370.10(a)(2)(ii).

[5] *See* 2-NFEJ_ER-289 (EPA's acknowledgment that "individuals who live or work near manufacturing, processing, use or disposal sites" may face greater exposures and risks); NFEJ_PA-56–61 (¶¶ 2-8), 66 (compiling information from EPA's National Air Toxics Assessment database and linking it to TRI data).

(Mar. 16, 1976). Congress recognized that "[w]hile individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards" posed by chemicals in particular contexts, none "ha[d] the authority to look comprehensively at the hazards associated with the chemical," as opposed to those hazards within each agency's narrower jurisdiction. *Id.* 2. TSCA gave EPA "the authority to look at the hazards in total." *Id.* 2.

Section 6 of TSCA establishes a two-step process for evaluating and managing the health and environmental risks posed by toxic chemicals. EPA first conducts a risk evaluation "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). If a risk evaluation shows that the chemical presents an unreasonable risk, EPA must issue regulations, known as risk-management rules, to eliminate that unreasonable risk. *Id.* § 2605(a); 1-NFEJ_ER-16, 201.

B. Congress's strengthening of TSCA's risk-evaluation and risk-management provisions

EPA conducted relatively few risk evaluations under the 1976 version of TSCA, which limited EPA to using the "least burdensome requirements" to regulate chemicals. *See* P.L. 94-469, 90 Stat. 2003, § 6 (Oct. 11, 1976). In 2016, Congress strengthened section 6 and related provisions to ensure "broad protection of human health and the environment." S. Rep. No. 114-67, at 1 (June 18, 2015); *see generally id.* 7-8, 11-14.

Congress added a new section 6(b) to clarify the proper scope of risk evaluations. Section 6(b)(4) says EPA "shall conduct risk evaluations … to determine whether a chemical substance presents an unreasonable risk to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). "[C]onditions of use" are "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). A "potentially exposed or susceptible subpopulation" is "a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance." *Id.* § 2602(12).

Congress explained that the amended section 6 "'de-couples' [EPA's] science-based risk decision about a chemical's safety under its intended conditions of use from [EPA's] decision on how to manage unreasonable risks where chemicals do not meet the safety standard under intended conditions of use."

S. Rep. 114-67 at 17.[6] In other words, EPA "must determine that a chemical meets the safety standard, or not, based solely on risk to human health and the environment—the integration of hazard and exposure information about a chemical—and not on the basis of other factors such as consideration of the costs or benefits of the substance or of possible restrictions on the substance." *Id.*

With respect to "potentially exposed and susceptible subpopulations," Congress emphasized that "identified risks specific to such populations must be addressed" in risk evaluations and that EPA's risk-management measures for chemicals it has evaluated must "protect [any relevant subpopulation] as well as the population as a whole from 'unreasonable risk.'" *Id.* at 7.[7]

Congress also enhanced EPA's authority to regulate chemicals that present unreasonable risk. Under section 6 as amended, "[i]f [EPA] determines [in a risk evaluation] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of those activities, presents an unreasonable risk of injury to health or the environment, [EPA] … shall … apply one or more of the following requirements … to the extent

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[6] "Safety standard" as used in the Senate bill refers to the same requirements that appear in the enacted section 6(b)(4). *See* S. Rep. 114-67 at 17 (the "Safety Standard" "ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to the chemical substance under the conditions of use.")

[7] The Senate bill used the term "populations" instead of "subpopulations."

necessary so that the chemical substance no longer presents such risk." 15 U.S.C. § 2605(a). The "requirements" range from flat bans to labeling and public notice requirements. *Id.* § 2605(a)(1)-(7). Before making a risk-management decision, EPA "shall consider" multiple alternatives and factors including "the costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions." *Id.* § 2605(c)(2).

In addition to strengthening section 6, Congress made other changes to enhance the scientific integrity of and the public's understanding of risk evaluations. Congress stated that EPA "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." *Id.* § 2625(h). Congress directed EPA to publish nontechnical summaries of each risk evaluation. *Id.* § 2625(j)(3). Congress also established a Science Advisory Committee on Chemicals (Science Committee) "to provide independent advice and expert consultation … with respect to the scientific and technical aspects" of EPA's implementation of TSCA. *Id.* § 2625(o)(2). The Committee "serves as a primary scientific peer review mechanism" for EPA's Office of Pollution Prevention and Toxics, which prepares risk evaluations, "and is structured to provide balanced expert assessment of chemicals and chemical-related matters." 2-NFEJ_ER-257.

Congress also provided that if EPA determines that a chemical substance presents no unreasonable risk, that determination has the effect of preempting certain further state and local regulation of the chemical. *See id.* § 2617(a)(1)(B)(i). Comprehensive, scientifically rigorous risk evaluations and risk-management rules are accordingly critical to ensuring that people are protected from the unreasonable risks posed by evaluated chemicals.

C. This Court's review of EPA's implementing regulations for risk evaluations

EPA issued new implementing regulations for risk evaluations in 2017, *see* 82 Fed. Reg. 33,726 (July 20, 2017), and environmental, public health, and labor groups including some of the Petitioners here challenged those regulations. *See Safer Chems., Healthy Families v. EPA*, 943 F.3d 397, 408-09 & n.5 (9th Cir. 2019). In 2019, this Court ruled that EPA had violated TSCA's plain language by purporting to exclude from its regulatory definition of "conditions of use" known, intended, and reasonably foreseeable future uses and disposals of chemicals that are no longer manufactured, processed, or distributed in commerce for those particular uses. *Id.* at 421, 423-25. This Court emphasized that EPA's discretion "to determine the conditions of use for each chemical … may only be exercised within the bounds of the statutory definition itself," and that EPA must apply the "conditions of use" definition Congress provided. *Id.* at 425.

This Court also considered and rejected an argument that EPA's scope regulations for risk evaluations were unlawful because they allowed EPA to "exclude[e] some conditions of use from consideration" in risk evaluations. *Id.* at 418-19; *see also id.* at 416 (referencing the regulations at 40 C.F.R. §§ 702.41 and 702.49). This Court did not read the regulations to give EPA such discretion. *Id.* at 419. Rather, it construed the regulations—and analogous language in section 6(b)(4)(D) that calls for EPA to identify the conditions it "expects to consider"—to refer simply to EPA's "role in determining what the conditions of use are for a particular substance." *Id.*

III. The Risk Evaluation

The Risk Evaluation lists fifty-three conditions of use of methylene chloride, each of which corresponds to an occupational setting (such as "domestic manufacture"), activity (such as "disposal"), or product category (such as "[c]onsumer use in adhesives or sealants"). *See* 1-NFEJ_ER-18–23, 198–201. EPA considered the risks posed by each condition of use as if they occur independently of the risks posed by others, without accounting for the fact that individuals can be exposed through more than one condition. *See* 1-NFEJ_ER-129–42; 2-NFEJ_ER-225, and *infra* Argument (Arg.) V.II. EPA determined that six occupational conditions of use of methylene chloride—including domestic

manufacture, processing as a reactant, processing for recycling, and disposal—present "no unreasonable risk" to workers. 1-NFEJ_ER-198–201.

The Risk Evaluation says EPA will consider risk-management measures for just those conditions of use that EPA found present an unreasonable risk. *See* 1-NFEJ_ER-201. This means that EPA will not consider protections for the approximately thirty thousand workers who are exposed to methylene chloride through the six conditions of use EPA found present no unreasonable risk.[8] Nor will EPA consider protections for other highly exposed and vulnerable groups, such as people who live near industrial and commercial emitters and are most threatened by the environmental releases the Risk Evaluation ignores, and people whose genetics make them more susceptible to developing cancer after exposure to methylene chloride. *See infra* Statement of the Case (Case Stmt.) III.B. Because EPA failed to combine individuals' simultaneous dermal and inhalation exposures and analyzed each condition of use independently of the others, *id.*, EPA is also unlikely to adequately protect the many people who are exposed both dermally and through inhalation, and through more than one of condition of use.[9]

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[8] *See* 1-NFEJ_ER-48–49 (sum of estimates under "Number of Workers," in rows for "Manufacturing," "Processing as a Reactant," "Laboratory Use," and "Waste Handling, Disposal, Treatment, and Recycling").

[9] EPA *will* consider regulatory protection for some less-exposed people, like those exposed solely through occasional use of a consumer product, because EPA found that such conditions of use present an unreasonable risk to health even when

The upshot is that unless this Court vacates EPA's no-unreasonable-risk determinations and orders EPA to revise the Risk Evaluation, many of the people who are most exposed and vulnerable to methylene chloride will receive no regulatory protection from the chemical under TSCA.

A. EPA's reliance on unsupported PPE-use assumptions and unexplained carcinogenicity estimates to understate methylene chloride's risks to highly exposed workers

To determine whether methylene chloride presents an unreasonable risk to workers, EPA relied on estimates of the chemical's carcinogenicity to humans, as well as estimates of how much methylene chloride each worker will be exposed to on the job. The main carcinogenicity estimate EPA used in the Risk Evaluation is substantially lower than ones used in earlier risk assessments for the same chemical. EPA also artificially reduced its exposure estimates for workers by making unsupported assumptions about their PPE use.

EPA deemed a 1-in-10,000 risk of contracting cancer due to methylene chloride exposure to be "unreasonable" in occupational settings. *See* 1-NFEJ_ER-183, 214. To determine which workers would exceed that threshold, EPA developed an inhalation unit risk (IUR) figure—an estimate of the increased cancer

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considered independently (e.g., based on an assumption that no individual exposed through use of the product will be exposed to the chemical in any other way). *See, e.g.,* 1-NFEJ_ER-201 (listing products EPA determined present an unreasonable risk, such as "arts, crafts, and hobby materials glue"); *see also infra* Arg. V.II.

risk associated with exposure to 1 milligram per cubic meter (mg/m3) of methylene chloride through inhalation over a working lifetime. *See* 1-NFEJ_ER-155–57.[10] EPA then multiplied the IUR by its estimates of how much of the chemical each worker would be exposed to. *See* 1-NFEJ_ER-157.

1. EPA's reliance on a carcinogenicity estimate that is considerably less protective than the ones used in past risk assessments for methylene chloride

EPA used an IUR that is almost thirty times lower, and thus less protective, than the one OSHA used in its own occupational risk assessment for methylene chloride—even though OSHA's was based on the same underlying data. *See* 2-NFEJ_ER-259 (Science Committee comments); Jan. 19, 2021 Decl. of Adam M. Finkel (Finkel Decl.) ¶¶ 7-9[11]; *see also infra* Arg. IV. The IUR EPA used is also lower than the IUR used in EPA's own previous risk assessments for methylene chloride. Finkel Decl. ¶ 10, 2-NFEJ_ER-305; 1-NFEJ_ER-155.

2. EPA's reliance on assumptions about worker PPE use to lower its risk estimates and avoid unreasonable-risk determinations for six occupational conditions of use

To estimate how much risk methylene chloride poses to workers, EPA first used information on measured or modeled methylene chloride levels in each

[10] EPA sometimes refers to inhalation unit risk using the smaller unit of micrograms per cubic meter (µg/m3). *See, e.g.*, 1-NFEJ_ER-210.

[11] Petitioners have moved to supplement the record with this declaration, which converts key figures into common terms to help the Court compare them. *See* Jan. 25, 2021 Mot. to Complete and Supp. the R. (Mot. to Complete), Arg II.

occupational setting to estimate how much of the chemical workers would be exposed to during their shifts. 1-NFEJ_ER-38–39. EPA multiplied those exposure estimates by the IUR to estimate cancer risk, and also compared the exposure estimates to other standards designed to account for the risks of liver disease and other noncancer health effects. *See* 1-NFEJ_ER-4, 13, 123, 129–42, 155–57.

These calculations show that methylene chloride presents an unreasonable risk to workers in all occupational conditions of use, based on risks of cancer and other health effects. *See* 1-NFEJ_ER-128–42 ("[r]isk [e]stimates for [n]o PPE" cols.).[12] But EPA did not rely on those calculations to determine whether methylene chloride poses an unreasonable risk to workers. Instead, it reduced exposure levels for all workers in many conditions of use, including the six for which EPA found no unreasonable risk, based on the assumption that those workers will be provided with and protected by two forms of PPE: bulky, expensive supplied-air respirators and chemical-resistant gloves. *See* 1-NFEJ_ER-183. EPA assumed that supplied-air respirators would reduce workers' inhalation exposures by a factor of 25 or 50 (depending on the level of protection EPA assumed the respirator would provide), and that chemical-resistant gloves would reduce workers' dermal exposures by a factor of 5 to 20 (depending

[12] The gray highlights in EPA's tables signify exposure levels EPA found were high enough to present an unreasonable risk. *See* 1-NFEJ_ER-128. EPA uses the abbreviation CNS for central nervous system effects.

on the level of protection EPA assumed the gloves would provide). *Id.*[13] Those adjustments dramatically lowered the exposure estimates EPA relied on for its final determinations of whether methylene chloride presents an unreasonable risk. *See* 1-NFEJ_ER-129–42 ("[r]isk [e]stimates with PPE" cols.). After assuming universal use of respirators and gloves, EPA determined that six conditions of use, including domestic manufacturing, processing as a reactant, recycling, and disposal, present no unreasonable risk to workers. 1-NFEJ_ER-198–201.

The Risk Evaluation cites no data on the prevalence or efficacy of respirator or glove use among workers exposed to methylene chloride. EPA relied on its belief, "based on consideration of the OSHA regulations [governing methylene chloride]," that "PPE *might* be necessary to meet federal regulations." 2-NFEJ_ER-240 (emphasis added).

B. EPA's reliance on other assumptions and exclusions to understate methylene chloride exposures and associated health risks

EPA made other choices in the Risk Evaluation that had the effect of understating methylene chloride's risks to many people, including workers.

First, EPA chose to *exclude* methylene chloride releases into ambient air, water, and soil and the associated exposures and human health risks from its

[13] EPA refers to these as "protection factors" (PF) or "assigned protection factors" (APF). *See also, e.g.,* 1-NFEJ_ER-212 (explaining how a range of APFs for respirators affect EPA's estimates of how much methylene chloride each worker will breathe), 1-NFEJ_ER-46 (explaining EPA's PF ranges for gloves).

analysis. 1-NFEJ_ER-13; *infra* Arg. I. The exclusion of environmental releases means that EPA has ignored or, as to people who are also exposed in a setting EPA evaluated, like manufacturing plants, understated risks to everyone who encounters the chemical in the environment. The exclusion is especially harmful to people who live near large industrial and commercial facilities that release methylene chloride into the air. *See infra* Arg. II.A.

Second, EPA never adjusted its estimates to reflect the special susceptibility of a large subgroup—approximately one-third of the U.S. population—who because of their genetic makeup are more likely to develop cancer after being exposed to methylene chloride. 1-NFEJ_ER-178, 210; *infra* Arg. II.B.

Last, EPA understated methylene chloride's health risks by failing to combine different exposure routes and sources that contribute to risk. EPA did not combine individuals' inhalation and dermal exposures, even though those typically occur simultaneously. 2-NFEJ_ER-225; 1-NFEJ_ER-12; *see also infra* Arg. V.A. Nor did EPA account for the fact that people exposed to the chemical through one activity (such as while working in a manufacturing plant) may also be exposed in other ways (such as while breathing methylene-chloride-polluted air during their commute, living in a polluted area nearby, or handling a consumer product at home). 2-NFEJ_ER-225; see *also infra* Arg. V.B.

The cumulative effect of these errors and omissions is that the Risk Evaluation entirely ignores methylene chloride's risks to some people and grossly understates the risks to others. Because the Evaluation serves as the foundation for EPA's risk-management work, *see* 15 U.S.C. § 2605(a)(1); 1-NFEJ_ER-16, the errors and omissions will lead to an underinclusive risk-management rule that leaves people around the country—including workers and neighbors of large industrial emitters—needlessly exposed to a dangerous chemical.

STANDARD OF REVIEW

TSCA's judicial review provision incorporates most of the Administrative Procedure Act's (APA's) general review standards and thus requires courts to set aside EPA action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1)-(2); 15 U.S.C. § 2618(c)(1)(B). Agency action is arbitrary and capricious when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Judicial review, while "deferential," must be "thorough, probing, [and] in-depth." *Ranchers*

Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA, 415 F.3d 1078, 1093 (9th Cir. 2005) (internal quotation marks and citation omitted).

TSCA's judicial review provision also provides that for purposes of reviewing orders under section 6(i)(1)—like the one included in the Risk Evaluation, *see* 1-NFEJ_ER-198–99—"the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(II). Although this Court has characterized the APA's arbitrary-and-capricious standard as incorporating the substantial-evidence test, *ASSE Int'l, Inc. v. Kerry*, 803 F.3d 1059, 1072 (9th Cir. 2015), TSCA's substantial-evidence standard is "distinct" and "particularly demanding." *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 991-92 (D.C. Cir. 1988) (internal quotation marks and citations omitted).

When reviewing EPA's legal interpretations of TSCA, this Court follows the test in *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). *See Safer Chems.*, 943 F.3d at 422 (Nov. 2019). If "Congress has directly spoken to the precise question at issue," the Court must give effect to Congress's unambiguously expressed intent. *Id.* If the statute is "silent or ambiguous," this Court must determine whether EPA's position reflects a "permissible construction of the statute." *Id.* This Court "need not defer to [EPA] regulations … 'if they construe a statute in a way that is contrary to congressional intent or that frustrates congressional policy.'" *Id.*

(quoting *Akhtar v. Burzynski*, 384 F.3d 1193, 1198 (9th Cir. 2004)). This Court should give no deference to EPA's legal interpretations of laws it does not administer, like the Occupational Safety and Health (OSH) Act. *See Ardestani v. INS*, 502 U.S. 129, 148 (1991).

SUMMARY OF ARGUMENT

EPA has denied large segments of the public the protections Congress mandated in its 2016 amendments to TSCA. The Risk Evaluation ignores the risks methylene chloride poses to large segments of the public, and grossly understates risks to many of the people who are most exposed to and threatened by the chemical in their day-to-day lives.

The Risk Evaluation excludes all releases of the chemical to the environment and associated threats to human health, even though EPA acknowledges that those releases occur, and TSCA requires EPA to evaluate all exposures and risks associated with chemicals' conditions of use. EPA did not identify people who live near industrial and commercial sites that release methylene chloride as a more-exposed subpopulation, even though TSCA requires it to do so. EPA also never determined whether methylene chloride poses an unreasonable risk to people in these neighboring communities, or to people whose genetic makeup renders them more susceptible to developing cancer after exposure, even though TSCA requires

EPA to determine whether chemicals present an unreasonable risk to more exposed and more susceptible subpopulations.

EPA grossly understated risks to workers in high-exposure settings like manufacturing, by assuming—contrary to OSHA regulations and without citing record support—that those workers would be adequately protected by PPE. EPA never explained why the carcinogenicity estimate it used to determine occupational risks is almost thirty times lower than the one OSHA derived from the same data, even though EPA's Science Committee and others requested an explanation, and EPA is required to provide one. EPA also did not combine exposures to account for the fact that many people are exposed through simultaneous inhalation and skin contact, and can also be exposed through more than one condition of use, even though TSCA requires EPA to consider combinations of activities that may present an unreasonable risk and to integrate available exposure information.

The Risk Evaluation is accordingly contrary to TSCA's text, unsupported by substantial evidence in the record, and arbitrary. To enforce Congress's mandates and ensure that EPA fully accounts for methylene chloride's risks and goes on to eliminate all unreasonable risk, the Court should vacate EPA's findings of no unreasonable risk and order EPA to revise the Risk Evaluation.

ARGUMENT

I. EPA violated TSCA and acted arbitrarily and without substantial evidence by excluding releases of methylene chloride to the environment

A. TSCA requires EPA to evaluate releases to the environment and associated exposures and risks

Each year, industrial facilities across the country release millions of pounds of methylene chloride into our ambient air, water, and land. 2-NFEJ_ER-301; *supra* nn.4-5. EPA understood that these environmental releases are caused by activities the agency identified as among the "conditions of use" of methylene chloride, and that the releases can lead to additional human exposures.[14] *See* 1-NFEJ_ER-13 ("[E]xposures to the general population may occur from conditions of use due to releases to air, water, or land"); 2-NFEJ_ER-288 ("[E]xposures to the general population may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use.").

TSCA requires risk evaluations to determine whether each chemical "presents an unreasonable risk of injury to health or the environment … under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). In so doing, EPA "shall integrate and assess available information on … exposures for the conditions of use of the

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[14] EPA has asserted that it "does not consider [methylene chloride] spills or leaks"—a subset of environmental releases—"to constitute circumstances under which [methylene chloride] is manufactured, processed, distributed, used, or disposed of, within TSCA's definition of 'conditions of use.'" 2-NFEJ_ER-221. That is contrary to *Safer Chemicals*, where this Court confirmed that "spills, leaks, and other uncontrolled discharges" "qualify as 'disposals.'" 943 F.3d at 426.

chemical substance." *Id.* § 2605(b)(4)(F)(i). TSCA accordingly required EPA to consider all exposures that result from methylene chloride's conditions of use and associated risks to health and the environment, including exposures and risks from known releases to the environment.

EPA concedes that it "did not evaluate hazards or exposures to the general population … and as such the unreasonable risk determinations for the relevant conditions of use do not account for exposures to the general population." 1-NFEJ_ER-13. The Risk Evaluation accordingly includes no analysis of the health risks associated with direct exposure to environmental releases, such as when people breathe methylene chloride pollution in the ambient air, or of the additional risks associated with methylene chloride's depletion of the ozone layer.

The only rationale EPA gives for excluding environmental releases, exposures, and risks is that TSCA allows it to "tailor" risk evaluations to ignore pollution that is "under the jurisdiction of" other laws it administers, and that either is or "could be" regulated under those other laws. 1-NFEJ_ER-24–27, ER 13.

EPA is wrong. TSCA shows that "Congress knows how to craft an exception when it intends one." *Jonah R. v. Carmona*, 446 F.3d 1000, 1007 (9th Cir. 2006). TSCA's "chemical substance" definition includes specific, narrow carveouts for substances and materials regulated for specified purposes under other

federal laws.[15] Apart from those definitional exclusions, which are not at issue here, nothing in TSCA authorizes EPA to exclude releases, exposures, and risks associated with chemicals' conditions of use from its risk evaluations. To the contrary, section 6 expressly *prohibits* EPA from considering "costs or other nonrisk factors," including the existence of and potential for regulation under other laws, when evaluating risks. 15 U.S.C. § 2605(b)(4)(F)(iii); *see also* S. Rep. No. 114-67 at 17 ("costs or nonrisk factors" means EPA cannot consider "factors such as consideration of costs or benefits of the substance *or of possible restrictions on the substance*" (emphasis added)).

EPA cites section 6's requirement that EPA identify the "hazards, exposures, [and] conditions of use … [it] expects to consider." 1-NFEJ_ER-24 (citing 15 U.S.C. § 2605(b)(4)(D)). But this Court recognized—nine months before EPA published the Risk Evaluation—that such language does not give EPA the discretion to exclude known exposures from identified conditions of use. *Safer Chems.*, 943 F.3d at 419. EPA's role is to "determin[e] what the conditions of use *are* for a particular substance," *id.* (emphasis added)—not to exclude uses that fall within TSCA's "conditions of use" definition and associated exposures and risks.

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[15] *See* 15 U.S.C. § 2602(2)(b)(ii), (iv)-(vi) (excluding specified substances, or uses thereof, regulated under the Federal Insecticide, Fungicide, and Rodenticide Act; Atomic Energy Act; Internal Revenue Code; and Federal Food, Drug, and Cosmetic Act).

EPA also cites section 9(b)(1), which concerns TSCA's relationship to other federal laws EPA administers. *See* 1-NFEJ_ER-24; 15 U.S.C. § 2608(b)(1). Section 9(b)(1) requires EPA to "coordinate actions taken under" TSCA with actions under other laws, and says that if EPA finds an unreasonable risk "could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, [EPA] shall use such authorities to protect against such risk unless [EPA] determines … that it is in the public interest to protect against such risk" under TSCA. *Id.* § 2608(b)(1). EPA cannot know whether unreasonable risk can be "eliminated or reduced to a sufficient extent" under other laws until it completes a lawful, comprehensive section 6 risk evaluation that identifies all unreasonable risk posed by a chemical.[16]

In short, TSCA requires EPA to evaluate all environmental releases, exposures, and risks that stem from methylene chloride's conditions of use.

B. Other federal laws have not eliminated the environmental releases EPA excluded and provide no equivalent protection to the public

Because TSCA requires EPA to account for all exposures and risks that stem from methylene chloride's conditions of use, the Court need not consider EPA's references to other federal laws to conclude that EPA violated TSCA by excluding

[16] Section 9(b) also calls for EPA to consider "costs and efficiencies," *id.* § 2608(b)(2), which EPA cannot do in risk evaluations. *Id.* § 2605(b)(4)(A).

environmental releases from the Risk Evaluation. In any event, the references just underscore why the exclusion was unlawful.

To begin with, millions of pounds of methylene chloride are released to air, water, and soil each year. *Supra* Case Stmt. I & nn.4-5. These releases continue to expose people to methylene chloride and contribute to environmental and human health risks notwithstanding the existence of the other federal laws EPA claims "address[]" the releases. *Contra* 1-NFEJ_ER-28.

The other laws EPA cites also do not call for anything close to the comprehensive risk-evaluation and risk-management process TSCA mandates for toxic chemicals. All were on the books when Congress amended and strengthened TSCA in 2016, and each applies to a specific medium, such as air, surface water, public drinking water, or solid waste.[17] None requires EPA to publish a comprehensive evaluation of methylene chloride's risks to health and the environment, including risks to potentially exposed or susceptible subpopulations, and go on to eliminate all unreasonable risks.

Take, for example, the Clean Air Act hazardous air pollutant (HAP) provisions EPA claims give it "comprehensive authority to regulate [methylene chloride] emissions to ambient air." 1-NFEJ_ER-28. The HAP provisions

[17] *See* 42 U.S.C. § 7401(b) (Clean Air Act); 33 U.S.C. § 1251(a) (Clean Water Act); 42 U.S.C § 300f (Safe Drinking Water Act); 42 U.S.C § 6901 (Resource Conservation and Recovery Act).

authorize EPA to regulate only very large sources and select smaller ones whose regulation EPA finds particularly warranted.[18] They also require EPA to account for the costs of capping emissions when setting emissions standards, *see* 42 U.S.C. § 7412(d)(2), whereas TSCA requires EPA to evaluate chemicals' risks "*without* consideration of costs or other non-risk factors," 15 U.S.C. § 2605(b)(4)(A) (emphasis added), and to eliminate any unreasonable risks it finds, *id.* § 2605(a).

During its early work on the Risk Evaluation, EPA also cited the Clean Air Act as a basis for refusing to evaluate methylene chloride's ozone-depleting effects, which harm the environment and increase the risk of health harms like skin cancer and cataracts. *See* 2-NFEJ_ER-252; 2-NFEJ_ER-293 n.20; 2-NFEJ_ER-286. EPA claimed that those effects are "adequately assessed and effectively managed under" Title VI of the Act, 1-NFEJ_ER-286, but methylene chloride is not regulated under Title VI. *See* 42 U.S.C. § 7671a (listing the regulated substances).[19] The Clean Air Act does not call for EPA to do the comprehensive evaluation of methylene chloride's risks (across all media) that TSCA mandates, or

[18] *See* 42 U.S.C. § 7412(a) (definitions), (c)(1)-(3), (d) (emissions-standards requirements).

[19] That some uses of methylene chloride are designated "acceptable substitutes" for other ozone-depleting substances under the Act's Significant New Alternatives Program, 1-NFEJ_ER-202, does not mean the designated uses present no unreasonable risk. It just means EPA has found those uses are relatively less ozone-depleting than some alternatives. *See* 42 U.S.C. § 7671k(c).

require EPA to eliminate unreasonable risk as TSCA does. The same goes for the other federal laws EPA invokes.[20]

By excluding environmental releases, EPA violated TSCA's requirement to account for all exposures and risks to health and the environment that stem from methylene chloride's conditions of use, *see* 15 U.S.C. §§ 2602(4), 2605(b)(4)(A), 2605(b)(4)(F)(i), and entirely ignored risks to many of the people Congress directed EPA to inform, *see id.* § 2625(j)(3), and protect through risk evaluations and risk-management rules.

II. EPA violated TSCA and acted arbitrarily and without substantial evidence by failing to identify and determine risks to some potentially exposed and susceptible subpopulations

TSCA requires risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health … *including an unreasonable risk to a potentially exposed or susceptible subpopulation* identified as relevant to the risk evaluation by [EPA]." 15 U.S.C. § 2605(b)(4)(A) (emphasis added); *see also id.* § 2605(b)(4)(D). "Potentially exposed or susceptible subpopulation[s]" are "group[s] of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than

[20] For example, the Safe Drinking Water Act provisions apply only to specified kinds of public water systems, 42 U.S.C. §§ 300f(4), 300g, and require EPA to account for the costs of limiting exposures and risks. *See id.* § 300f(1)(C)(i)-(ii).

the general population of adverse health effects from exposure." *Id.* § 2602(12). Risk evaluations must also use the "best available science." *Id.* § 2625(h).

The Risk Evaluation does not identify as a "potentially exposed" subpopulation people who live and work near industrial and commercial emitters of methylene chloride, and does not determine whether methylene chloride presents an unreasonable risk to either that group or the "potentially. . . susceptible" group of people who are especially likely to develop cancer after being exposed because of their genetic makeup. This is unlawful.

A. EPA unlawfully failed to identify as more exposed and determine risks to the communities neighboring industrial and commercial emitters of methylene chloride pollution

In the early phases of its work on the Risk Evaluation, EPA acknowledged that people who live near industrial and commercial sources of methylene chloride are potentially exposed and susceptible subpopulations because they "may experience greater exposures due to their proximity to conditions of use … that result in releases to the environment and subsequent exposures." 2-NFEJ_ER-299; 2-NFEJ_ER-289; *see also* 1-NFEJ_ER-249–52. The Science Committee recommended that EPA treat people "living in close proximity to large and small emissions sources" as a "potentially exposed subpopulation[]." 2-NFEJ_ER-265. Public commenters made similar requests. *E.g.*, 2-NFEJ_ER-283–84.

EPA accordingly should have identified neighboring communities as a "potentially exposed … subpopulation," *see* 15 U.S.C. § 2602(12), and determined whether methylene chloride poses an unreasonable risk to that subpopulation, *id.* § 2605(b)(4)(A). The Risk Evaluation does not do so. 1-NFEJ_ER-178–79. The only reason EPA gives for failing to identify as especially exposed and determine risks to neighboring communities is the one it gave for excluding the environmental releases that threaten those communities—that those releases are "under the jurisdiction of" and "addressed by" other laws. *See* 2-NFEJ_ER-249–51; *supra* Arg. I. But TSCA requires EPA to evaluate risks to subpopulations that face "greater exposure" to toxic chemicals regardless of whether those chemicals are or could be regulated under other laws, 15 U.S.C. §§ 2602(12); 2605(b)(4)(A), and other laws have not eliminated the exposures. *Supra* Arg. I. EPA also has not identified any law besides TSCA that requires it to identify, give special consideration to, and eliminate unreasonable risks to potentially exposed and susceptible subpopulations. *See* 2-NFEJ_ER-249–51.

B. EPA unlawfully failed to determine risks to the large subpopulation whose genetics make them especially susceptible to methylene chloride exposure

Roughly a third of humans have a genetic condition—a form of enzyme labeled GSTT1 +/+—that makes them especially likely to develop cancer following exposure to methylene chloride. 1-NFEJ_ER-178–79. The Risk

Evaluation identifies this group as a "susceptible" subpopulation, 1-NFEJ_ER-179, but EPA did not base the cancer-risk threshold it used to determine unreasonable risk on that group's greater susceptibility. *See* 1-NFEJ_ER-117 (discussing EPA's cancer-risk modeling). Rather, EPA used a data distribution for the full human population, which is dominated by people who do not have the special susceptibility. 1-NFEJ_ER-210 ("Sampling of the full distribution of GSTT genotypes in the human population … was done to derive the IUR for liver and lung tumors."). This made a big difference: an IUR based on the most genetically susceptible group would have been about 75% higher, and accordingly 75% more protective of human health. 2-NFEJ_ER-235; *see also infra* Arg. IV.

EPA's decision to base its IUR on data for the full population marks a departure from its two previous risk assessments for methylene chloride, its 2011 Integrated Risk Information System (IRIS) assessment and its 2014 assessment of the chemical's paint-stripping uses under TSCA.[21] The 2011 assessment used an IUR "derived specifically for" the subpopulation that is most genetically susceptible—people with the GSTT1 +/+ form of the enzyme—in order to "provide protection for the population that is hypothesized to be most sensitive to

[21] The IRIS program develops chemical risk assessments to support the work of EPA and other agencies. *See* EPA, *Basic Information About IRIS*, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (visited Jan. 20, 2021); *supra* n.4 (discussing judicial notice).

the carcinogenic effect." 2-NFEJ_ER-308. EPA took that same approach in the 2014 assessment.[22]

Science Committee and public commenters on EPA's draft risk evaluation noticed and criticized EPA's departure from its past practice. 1-NFEJ_ER-234–35, 237; 1-NFEJ_ER-261. In response, EPA has asserted that "because the IUR is based on the lower 95% confidence limit, EPA considers the value to adequately include risk for the GSTT1 +/+ population and that [sic] the previous IUR was more conservative than necessary because it combined both the GSTT1 +/+ population and the lower 95% confidence limit." 1-NFEJ_ER-118; *see also* 2-NFEJ_ER-235, 237 (similar). But EPA's own *Guidelines for Carcinogen Risk Assessment* provide for it to use the lower 95% limit for cancer-risk assessment generally, 2-NFEJ_ER-310, and to "derive *separate* estimates for susceptible populations … so that these risks can be explicitly characterized." 2-NFEJ_ER-311 (emphasis added).[23]

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[22] 2-NFEJ_ER-305 (2014 assessment) ("The mean of the distribution of candidate IUR values from the most sensitive (GST-T1+/+) genotype (i.e., the group that would be expected to be most sensitive to the carcinogenic effects of [methylene chloride]) was chosen as the IUR for liver and lung tumors.").

[23] *See also* 2-NFEJ_ER-312 ("data should be analyzed with an eye toward adjusting the general population estimate for susceptible individuals"). The *Guidelines* recognize that susceptible populations in this context include "those bearing a particular genetic susceptibility." 2-NFEJ_ER-311.

By failing to determine whether methylene chloride presents an unreasonable risk to the large subpopulation that is most genetically susceptible to exposure and to base its risk estimates on that group's special susceptibility, EPA violated TSCA's mandates that it "determine whether [methylene chloride] presents an unreasonable risk of injury. . . to a potentially exposed or susceptible subpopulation … under the conditions of use," 15 U.S.C. § 2605(b)(4)(A), and base its risk evaluations on the "best available science," 15 U.S.C. § 2625(h).[24] EPA also departed arbitrarily from its past practice and guidance on risk assessment and its Science Committee's advice. *See NRDC v. Pritzker*, 828 F.3d 1125, 1139-40 (9th Cir. 2016) (agency acted arbitrarily by drawing a conclusion that was in direct conflict with its own subject-matter experts' conclusions and recommendations); *Trout Unlimited v. Lohn*, 645 F. Supp. 2d 929, 957 (D. Or. 2007) (it was "contrary to the record and the best available science" for agency to

[24] *See* S. Rep. No. 114-67 at 9 (TSCA's best available science standard reflects the "significant value" in EPA's use of available "peer reviewed information" and "consistent data evaluation procedures" for risk evaluations); *cf. Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988) (agency violated the Endangered Species Act's (ESA's) requirement to use the "best scientific and commercial data available" by "ignor[ing] available biological information" on threats to species); *Consol. Delta Smelt Cases*, 717 F. Supp. 2d 1021, 1061-62 (E.D. Cal. 2010) (the ESA's best available science standard prevents an agency from "disregard[ing] available scientific evidence better than the evidence on which it relies").

rely on a conclusion its peer reviewers found "had insufficient scientific support").[25]

III. EPA violated TSCA, misconstrued OSHA regulations, and acted arbitrarily and without substantial evidence by assuming that workers would be protected by PPE

EPA's determinations of methylene chloride's risks to workers, including for the six conditions of use that EPA found present no unreasonable risk, rest on EPA's assumption that workers engaged in those uses would be provided with PPE—specifically, expensive and bulky supplied-air respirators and chemical-resistant gloves. That assumption has no basis in law or fact. First, the assumption violates TSCA, which permits EPA to consider risk-management tools such as PPE only *after* it completes a risk evaluation and determines whether a chemical presents unreasonable risk. Second, EPA's risk determinations rest on a misinterpretation of OSHA regulations, which unambiguously do not require the use of respirators or gloves in the circumstances EPA assumed. Finally, there is no

[25] *See also id.* at 964 (compiling additional cases from this Court and others "finding that agencies erred in disregarding the best available science and the opinions of their own scientists or scientific advisors"); *Consol. Delta Smelt Cases*, 717 F. Supp. 2d at 1061-62 (explaining that "the judicial review process is not one of blind acceptance" and that courts "routinely perform substantive reviews of record evidence to evaluate the agency's treatment of best available science," and compiling additional cases from this Court and others); *Physicians for Soc. Responsibility v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020) (discussing the "critical role played by EPA's scientific advisory committees" in ensuring EPA's compliance with TSCA and other federal laws' "best available science" mandates).

substantial evidence in the record that workers will be provided with this equipment, let alone be adequately trained on and protected by it.

A. OSHA's regulation of methylene chloride exposures in the workplace

EPA does not write on a clean slate when evaluating methylene chloride's occupational risks. OSHA and the National Institute for Occupational Safety and Health (NIOSH) have a fifty-year history of evaluating workplace exposures under the Occupational Safety and Health Act (OSH Act). *See* 29 U.S.C. §§ 651 *et seq.* Because EPA invoked OSHA's methylene chloride standard to explain and defend its evaluation, *see, e.g.*, 1-NFEJ_ER-14, 39–40; 2-NFEJ_ER-241–44, 246–47, it is important for this Court to understand what the standard does, and does not, require.

OSHA first regulated methylene chloride in 1971, when it adopted a permissible exposure limit (PEL) of 500 parts per million (ppm), averaged over an eight-hour workday, to protect workers from the chemical's acute neurological effects. *See* Occupational Exposure to Methylene Chloride, 62 Fed. Reg. 1494, 1496 (Jan. 10, 1997). When evidence that methylene chloride causes cancer emerged in the 1980s, Petitioner United Steelworkers and other unions petitioned OSHA to further regulate the chemical. *Id.* at 1497.

In 1997, after extensive rulemaking proceedings, OSHA lowered the methylene chloride PEL from 500 to 25 ppm averaged over an eight-hour workday

and adopted other worker protections. *See* 29 C.F.R. § 1910.1052(c)(1). OSHA concluded that its PEL was not fully health protective, and that even at 25 ppm employees would remain exposed to "clearly significant" and "unacceptably high" cancer risks, but that employers could not feasibly reduce exposures further at that time. 62 Fed. Reg. at 1562-63.

To determine the degree of control necessary to protect workers, OSHA requires employers to measure the levels of exposure "which occur[] or would occur if the employee were not using respiratory protection." 29 C.F.R. § 1910.1052(b) (defining "employee exposure"). If measured exposures without the use of respirators exceed the PEL, employers must first "institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the PEL[]." *Id.* § 1910.1052(f)(1). Only if "engineering controls and work practices … are not sufficient to reduce employee exposure to or below the [PEL]" may an employer "supplement them by the use of respiratory protection."[26] *Id.* There is no requirement to use respirators to further reduce exposure below the PEL. *See* 62 Fed. Reg. at 1581; *see also Sec'y of Lab., U.S.*

[26] Respirators and gloves are forms of PPE. Engineering controls, such as ventilation hoods positioned over an emissions source, are a different type of protection designed to remove exposures at the source. *See* 2-NFEJ_ER-302–03. Work-practice controls adjust worker schedules to reduce the time they spend exposed to hazards.

Dep't of Lab. v. Seward Ship's Drydock, Inc., 937 F.3d 1301, 1306, 1308 (9th Cir. 2019) (recognizing that respirators are not required below an OSHA PEL).

B. EPA's assumption that workers will universally use and be protected by PPE is contrary to TSCA

TSCA requires EPA to use the "best available science," 15 U.S.C. § 2625(h), and to determine whether chemicals present an unreasonable risk without consideration of PPE or other risk-management measures, *see supra* Case Stmt. II. The Risk Evaluation violates both requirements.

First, EPA's assumptions about PPE use run counter to Congress's deliberate separation of the risk-evaluation and risk-management processes. TSCA Section 6(b) provides that EPA "shall conduct risk evaluations … to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Only after completing a risk evaluation and determining that a chemical presents an unreasonable risk may EPA assess its options for managing that risk pursuant to Sections 6(a) and 6(c). 15 U.S.C. § 2605(a), (c)(2). Those sections provide that EPA "shall consider" multiple risk-management tools pursuant to factors prescribed in the statute, and

"shall … apply one or more" of those tools "so that the chemical … no longer presents [unreasonable] risk." *Id.*[27]

Congress separated risk management from risk evaluation to ensure that the determination of whether a chemical poses unreasonable risk is made based on health and environmental effects only. *See* 15 U.S.C. § 2605(b)(4) (prohibiting EPA from considering "non-risk factors" in risk evaluations). Decisions about how to control that risk, which necessarily implicate "costs [and] other non-risk factors," can be made only during risk management. *Id.* § 2605(b)(4), 2605(c)(2) (requiring EPA to consider the "the costs and benefits" of different regulatory options before issuing a risk-management rule).

Here, EPA bypassed the risk-management process for six occupational conditions of use by assuming, in the Risk Evaluation, that PPE would eliminate the unreasonable risks to workers that it had calculated. *See supra* Case Stmt. III.A; Arg. III.A. EPA thus impermissibly selected a risk-management approach in the Risk Evaluation itself—without comparing the relative efficacy of PPE to other

[27] The OSH Act mandates a similar, two-step process for risk evaluation and risk management. First, OSHA evaluates whether a chemical hazard poses a significant risk of material impairment at levels of exposure permitted in the workplace. *See Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (requiring that OSHA find a significant risk as a precondition to regulation). Only if a chemical presents a significant risk does OSHA go on to consider whether it is economically and technologically feasible for employers to reduce that risk. *See id.*

potential control methods, and without any mechanism for ensuring that the assumed PPE would actually be provided and used. *See* 2-NFEJ_ER-245 (acknowledging that EPA is "not recommending or requiring" the use of respirators). EPA's approach conflates risk evaluation with risk management and denies tens of thousands of workers the protection Congress mandated.

EPA's PPE assumptions also violate TSCA's requirement, applicable to both risk evaluation and risk management, that EPA use "methods, protocols [and] methodologies … in a manner consistent with the best available science." 15 U.S.C. § 2625(h). The "best available science" for occupational risk assessment requires the measurement of worker exposures to chemicals without PPE. This approach is memorialized in every OSHA health standard, including its methylene chloride standard. *See* 29 C.F.R. § 1910.1052(b).[28] EPA's Science Committee concluded that the Agency's assumption of respirator use is "not supported by current research literature or industrial hygiene practice."[29] 2-NFEJ_ER-260.

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[28] *See also e.g.*, 29 C.F.R. § 1910.1001(b) (defining employee exposure in asbestos standard); *id.* § 1910.1025(d)(1)(i) (defining employee exposure in lead standard); *id.* § 1910.1048(b) (defining employee exposure in formaldehyde standard).

[29] In comments on the draft Risk Evaluation that Petitioners are moving to complete the record with, *see* Mot. to Complete, Arg I., NIOSH advised EPA that "[i]n occupational risk assessment, risks should be calculated without regard for respiratory protection." Mot. to Complete, Decl. of Randy Rabinowitz (Rabinowitz Decl.), Ex. A at 3.

Core industrial hygiene principles require the measurement of worker exposures, and hence risk, without regard to PPE use, so that PPE can be considered along with other, preferred forms of risk management pursuant to the "hierarchy of controls." This hierarchy, which "has been established industrial hygiene practice since the 1950s," prioritizes chemical elimination, substitution, engineering controls, and administrative controls over the use of PPE, and prohibits employers from relying on PPE until they have exhausted those preferred options. *See* 62 Fed. Reg. at 1582; 2-NFEJ_ER-302–03. In addition to being required by "[a]ll OSHA substance-specific health standards," 62 Fed. Reg. at 1582, the hierarchy of controls has been endorsed by NIOSH, the American Conference of Governmental Industrial Hygienists, the American Public Health Association, and others. *See* 2-NFEJ_ER-272; *see also Am. Iron & Steel Inst. v. Occupational Safety & Health Admin.*, 182 F.3d 1261, 1270 (11th Cir. 1999) (describing the hierarchy of controls as "the national consensus standard"). Here, EPA's default assumption—that all workers would be provided with, trained on, properly fitted for, and would wear supplied air respirators—directly conflicts with the hierarchy of controls.

When determining the best available science, "courts are not required to defer to an agency conclusion that runs counter to that of other agencies or individuals with specialized expertise in a particular technical area." *Consol. Delta*

Smelt Cases, 717 F. Supp. 2d at 1062; *see also* 15 U.S.C. § 2625(h)(5) (requiring EPA to consider "the extent of independent verification" of its "methodologies" when determining the "best available science"). There is broad consensus among occupational health and safety experts that worker exposures should be measured without PPE, and that PPE is a risk-management tool that should be used only in the absence of more effective controls. EPA's departure from that accepted methodology is fatal to the Risk Evaluation.

C. EPA's assumption that employers will provide workers with adequate PPE is predicated on a misreading of OSHA regulations and is arbitrary

EPA misinterprets OSHA's regulations to justify the PPE assumptions in the Risk Evaluation. EPA asserts in the Evaluation that workers "are typically protected by PPE … based on consideration of the OSHA regulations at 29 C.F.R. § 1910.1052, which sets the methylene chloride standard." 2-NFEJ_ER-241. EPA also says it "does not believe it should assume that workers are unprotected by PPE where such PPE *might* be necessary to meet federal regulations." 2-NFEJ_ER-242–43 (emphasis added). But OSHA regulations do not require respirator use at the levels of exposure EPA has determined present unreasonable risks to workers, because the levels of exposure that pose unreasonable risk are below the OSHA PEL. Nor do OSHA regulations require glove use to protect against the cancer risks posed by dermal absorption of methylene chloride. EPA's assumptions to the

contrary are not entitled to any deference. *See Sierra Club v. U.S. Army Corps of Eng'rs*, 701 F.2d 1011, 1030 (2d Cir. 1983) ("[T]he court may properly be skeptical … if the responsible agency has apparently ignored the conflicting views of other agencies having pertinent expertise"); *Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 150 (1991) (finding that OSHA is "entitled to substantial deference" in construing its own regulations).[30]

The OSH Act requires employers to comply with OSHA standards, but not to exceed them. 29 U.S.C § 654(a)(2); *see also* 62 Fed. Reg. at 1581 (requiring the use of respirators "only if occupational exposures [to methylene chloride] … are likely to exceed the … PEL"). Under OSHA's methylene chloride standard, employers must reduce exposures to the PEL of 25 ppm and do so using engineering and work practice controls alone wherever feasible. 29 C.F.R. § 1910.1052(f)(1).[31]

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[30] EPA received comments from OSHA and NIOSH and has claimed that those agencies "contributions during [interagency] review are reflected in the Draft and Final Risk Evaluation." 2-NFEJ_ER-230. EPA refused to add those comments to the record, and Petitioners have filed a concurrent motion to complete the record with them. *See* Mot. to Complete Arg. I. and Decl. of Randy Rabinowitz (Rabinowitz Decl.). In its comments, which it disclosed to Petitioners, NIOSH told EPA that "it is NOT plausible to assume that every worker would be in a respirator." Rabinowitz Decl., Ex. A at 3.

[31] An employer who complies with the OSHA standard is also considered to be complying with the OSH Act's general duty clause, which requires employers to protect workers from "recognized hazards." *See* 29 U.S.C § 654(a)(1); 29 C.F.R. § 1910.5(f). OSHA has advised its inspectors that "section 5(a)(1) shall not

However, both OSHA and EPA have found that exposure to methylene chloride at levels below OSHA's 25 ppm PEL poses an unacceptable risk. *See* 2-NFEJ_ER-251 (acknowledging potential "health risks … from exposures below the PEL); 62 Fed. Reg. at 1516, 1562; Proposed Rule: Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7470 (Jan. 19, 2017) (acknowledging that "[t]he OSHA PEL is considerably higher than the levels at which EPA identified risks of concern for methylene chloride … and would not be protective for the unreasonable risks identified"). For liver effects, EPA found that anyone exposed to methylene chloride at levels above 0.48 ppm, averaged over a twenty-four-hour period, would face an unreasonable risk. 1-NFEJ_ER-123[32]; Finkel Decl. ¶¶ 11-14 (explaining how to convert EPA's measurement units). EPA also calculated unreasonable cancer risks below the PEL. 1-NFEJ_ER-123; Finkel Decl. ¶¶ 7-8. EPA assumed

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normally be used to impose a stricter requirement" than required by an OSHA PEL. OSHA Regulatory Directive, *Inspection Procedures for the Respiratory Protection Standard* at 5 (June 2014), https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-00-158.pdf; *supra* n.4 (discussing judicial notice).

[32] To calculate unreasonable risk, EPA first calculated a "human equivalent concentration" (HEC) of 4.8 ppm (calculated based on the level above which adverse effects were observed in animal studies), and then applied a ten-fold uncertainty factor, meaning exposures above 0.48 ppm over a twenty-four-hour period were deemed unreasonable. 1-NFEJ_ER-5, 123; Finkel Decl. ¶ 12. This level is far below the PEL, although those figures are expressed in the Risk Evaluation using different units of measurement.

in the Risk Evaluation that employers will provide workers with PPE sufficient to eliminate these unreasonable risks, even though OSHA imposes no duty to do so.

EPA's assumptions about worker glove use also misconstrue OSHA regulations. EPA finds that dermal exposure to methylene chloride poses unreasonable risks of central nervous system and liver effects for all occupational conditions of use in the absence of PPE, but goes on to assume—for purposes of its final risk determinations—that workers will avoid this risk by wearing sufficiently protective gloves. 1-NFEJ_ER-165–70.[33] OSHA's methylene chloride standard requires glove use only "[w]here needed" to protect employees from "skin or eye irritation"—not chronic liver and neural effects. 29 C.F.R. § 1910.1052(h)(1). EPA cites no evidence that the level of glove use required to protect against irritation would also protect against long-term central nervous system and liver effects.

EPA also misconstrues OSHA's Hazard Communication Standard, 29 C.F.R. § 1910.1200, which requires chemical manufacturers to prepare safety data sheets (SDSs) advising of a chemical's hazards and recommended methods for hazard control. EPA assumes that "OSHA regulations for … hazard communication will result in use of appropriate PPE" recommended in an SDS. 1-NFEJ_ER-14. EPA ignores the fact that OSHA has made clear that "*there is no*

[33] The gray highlights and bold text in the tables signify exposure levels EPA found were high enough to present an unreasonable risk. *See* supra n.12.

requirement for employers to implement the recommended controls" on an SDS. Hazard Communication, 77 Fed. Reg. 17,574, 17,693 (Mar. 26, 2012) (emphasis added). Because EPA's PPE assumptions "misconceive" the OSHA requirements EPA purports to rely upon, the risk determinations EPA predicated on those assumptions "may not stand." *Secs. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 94 (1943); *Rodriguez-Roman v. Immigr. & Naturalization Serv.*, 98 F.3d 416, 429 (9th Cir. 1996) (citation omitted) (an agency explanation that is "based upon … a misreading of the law" is "necessarily" arbitrary and capricious).

D. EPA's assumptions that workers will use and be protected by PPE are not supported by substantial evidence

In addition to misinterpreting OSHA regulations, EPA's assumptions about worker respirator and glove use are not "supported by substantial evidence in the record." 15 U.S.C. § 2618(c)(1)(B)(i)(II). EPA cites no evidence concerning the frequency or effectiveness of PPE use, and the Risk Evaluation disregards evidence from OSHA, NIOSH, the Science Committee, and EPA itself that contradicts EPA's PPE assumptions.

OSHA has consistently found respirators to be unreliable as protection against harmful chemicals, warning that respirators are "uncomfortable to wear, cumbersome to use, and interfere with communication in the workplace, which can

often be critical to maintaining safety and health." 62 Fed. Reg. at 1583.[34] This Court has upheld OSHA's findings that respirators are "woefully inadequate" to protect workers due to "problems with adequate facial fit, increased heat stress, reduced vision, increased breathing resistance, speech limitation, limited mobility, and excess weight." *ASARCO v. OSHA*, 746 F.2d 483, 496 n.27, 497 (9th Cir. 1984).[35]

EPA and OSHA have both acknowledged that, to function properly, respirators require periodic fit testing, medical testing, and employee training. 1-NFEJ_ER-183–84; 62 Fed. Reg. at 1607, 1582. However, a NIOSH study EPA cites in the Risk Evaluation shows that respirators are routinely used *without* the requisite training or testing.[36] EPA's assumption that "PPE is used in a manner that achieves the stated [protection factor]" ignores this NIOSH finding. 1-NFEJ_ER-184. A majority of the Science Committee agreed that "EPA's assumptions of PPE use likely do not reflect actual conditions in most workplaces." 2-NFEJ_ER-258;

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[34] *See also* Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite, 51 Fed. Reg. 22,612, 22,693 (June 20, 1986) (describing the limits of respirator use); Occupational Exposure to Respirable Silica, 81 Fed. Reg. 16,286, 16,293 (Mar. 25, 2016) (describing how OSHA health standards generally rely on the hierarchy of controls and limit respirator use).

[35] *See also Pub. Citizen Health Rsch. Grp. v. U.S. Dep't of Lab.*, 557 F.3d 165, 179 (3rd Cir. 2009) (discussing why respirators are strongly disfavored).

[36] *See* 2-NFEJ_ER-267 (NIOSH findings that only 59% of employers provided training on respirator use, and only 47% tested their employees' fitness to wear respirators); 1-NFEJ_ER-39.

see also 2-NFEJ_ER-264 (noting that "use of PPE will degrade over time, both within a daily work shift and over the course of a worker's career").

Even where respirators are accompanied by adequate testing and training, EPA has previously acknowledged that "not all workers may be able to wear respirators," or to wear them safely and effectively. *See* 82 Fed. Reg. at 7481. In its proposed ban on methylene chloride's paint-stripping uses, EPA declined to rely on respirators precisely because workers with impaired lung function—such as those with asthma, emphysema, and chronic obstructive pulmonary disease—"may be physically unable to wear a respirator," and workers with facial hair "cannot wear tight-fitting respirators" that require a face-to-respirator seal. *Id.*

The challenges associated with respirator use are particularly acute for methylene chloride, which passes through the filters of the most common and least expensive respirators. *See* 1-NFEJ_ER-40. As a result, OSHA's methylene chloride standard only permits the use of supplied-air respirators, "a relatively expensive type of respiratory equipment, requiring the employer not only to purchase the respirators themselves but also to install an air compressor and associated ductwork or rent cylinders containing breathing air." Methylene Chloride; Final Rule, 63 Fed. Reg. 50,712, 50,718 (Sept. 22, 1998); 29 C.F.R. § 1910.1052(g)(3)(i).[37] Given the added expense and difficulty of using supplied-

[37] An illustration of a supplied-air respirator is available at 2-NFEJ_ER-281.

air respirators, it defies common sense for EPA to assume that employers will voluntarily provide them in circumstances where OSHA does not require them.

Inexplicably, EPA made little effort to consider readily available information that could have confirmed whether its assumptions of respirator use were supported, even though TSCA and EPA's regulations required that consideration. *See* 15 U.S.C. § 2625(k) (EPA must "take into consideration … hazard and exposure information … reasonably available to [EPA]"); 40 C.F.R. § 702.33 (defining "reasonably available information"). OSHA requires employers who use methylene chloride to conduct initial monitoring of exposure levels, 29 C.F.R. § 1910.1052(d)(2), and, if exposures exceed half the PEL, to continue periodic monitoring, *id.* § 1910.1052(d)(3). Monitoring records must be accompanied by detailed industrial hygiene data, including on whether workers wore respirators. *Id.* § 1910.1052(m)(2)(ii)(E). Employers must retain this data for 30 years. *Id.* § 1910.1052(m)(2)(iv).

EPA therefore could have obtained monitoring and respirator use data from affected facilities, including by invoking its TSCA subpoena power if needed. *See* 15 U.S.C. § 2610(c) (authorizing EPA to "subpoena … the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary"). TSCA requires EPA to use that authority. 40 C.F.R. § 702.33 (defining "[r]easonably available information" to include

"information that EPA possesses *or can reasonably generate, obtain, and synthesize* for use in risk evaluations" (emphasis added)); *Asbestos Disease Awareness Org. v. Wheeler*, No. 19-00871-EMC, 2020 WL 7625445, at *19 (N.D. Cal. Dec. 22, 2020) (holding that EPA's failure to use its "significant statutory authority to require that … information be reported … runs contrary to its obligation to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA").

With respect to dermal exposures, EPA admits that it does "not know the actual frequency, type, and effectiveness of glove use in specific workplaces." 1-NFEJ_ER-51. For manufacturing, processing as a reactant, and several other conditions of use, EPA nonetheless assumed that workers would wear gloves with a protection factor (PF) of 20, the highest possible protection level, *see* 1-NFEJ_ER-46, 129–31—despite EPA's acknowledgment that "*the PF of 20 would usually not be expected to be achieved*," 1-NFEJ_ER-46 (emphasis added). Had EPA assumed no glove use (or even the use of gloves with a PF of 5), EPA would have concluded that methylene chloride presents an unreasonable risk to workers in every occupational condition of use. *See* 1-NFEJ_ER-167–68.

In short, "the record is entirely devoid of any evidence, much less substantial evidence, supporting" EPA's PPE assumptions. *Vance v. Heckler*, 757 F.2d 1324, 1325 (D.C. Cir. 1985). EPA effectively concedes this, stating that it will "increase

its effort to obtain information on PPE use for future risk evaluations." 2-NFEJ_ER-239. This promise to do better in the future provides no comfort to the workers who will be left exposed to unsafe levels of methylene chloride because EPA assumed, without evidence, that they would be adequately protected by PPE. EPA's "wishful thinking" is not a "substitute[] for substantial evidence." *Pub. Serv. Comm'n of Utah v. United States*, 356 U.S. 421, 428 (1958); *see also NRDC v. EPA*, 857 F.3d 1030, 1038 (9th Cir. 2017) (holding that an EPA finding based on "unsubstantiated assumptions" was "not supported by substantial evidence").

IV. EPA failed to adequately explain why it used estimates of methylene chloride's carcinogenicity that are considerably lower than ones used in past risk assessments

The Risk Evaluation assumes that methylene chloride is substantially less carcinogenic than past assessments of the chemical, without explaining the change. When establishing its methylene chloride standard in the late 1990s, OSHA completed a comprehensive evaluation of methylene chloride's cancer risks and found that exposure to methylene chloride at a concentration of 25 ppm over an eight-hour workday would result in approximately 3.62 additional cancer deaths per 1,000 workers. 2-NFEJ_ER-238; 62 Fed. Reg. at 1516. EPA's current estimate of methylene chloride's carcinogenicity (expressed as an IUR, or inhalation unit risk) is nearly thirty times lower (and thus less protective), even though EPA relied on the same underlying data as OSHA. 1-NFEJ_ER-123; 2-NFEJ_ER-259 ("The

[IURs] developed by EPA for this methylene chloride risk evaluation are less protective than previous dose-response assessments by EPA and OSHA, all of which relied on the same underlying data").[38]

What's more, EPA used different carcinogenicity estimates in different parts of the Risk Evaluation. To calculate risks from methylene chloride's use in paint and coating removal, EPA used the IUR from its 2014 risk assessment for methylene chloride, which is about eight times higher (and thus more protective) than the IUR used for all other conditions of use.[39] But methylene chloride is no less carcinogenic when processed as a reactant than it is when used to strip paint. EPA's "inconsistent analysis is arbitrary and capricious." *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015).

The Science Committee noted the wide variance in these carcinogenicity estimates and called on EPA to "explain why new [cancer] risks were derived and exactly how they differ from" what OSHA used in its assessment. 2-NFEJ_ER-259; *see also* 2-NFEJ_ER-270 (Committee member request for an explanation of "how methylene chloride just has sort of steadily gotten less and less potent as a

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[38] *See also* Finkel Decl. ¶¶ 7-10 (explaining how to convert the compared figures into common measurement units).

[39] *Compare* 1-NFEJ_ER-123 (providing IUR for non-paint-stripping uses of methylene chloride), *with* 1-NFEJ_ER-213 (providing separate IUR for paint-stripping uses), *and* 1-NFEJ_ER-192–93 (relying on separate IUR calculations to determine risk from paint stripping); *see also* Finkel Decl. ¶ 10 (calculating difference between EPA's paint-stripping and non-paint-stripping IUR figures).

carcinogen since 1997 when OSHA did the assessment, even though all of the assessments … used the same underlying data"). Petitioner United Steelworkers and other public commenters also noted the variations among the IURs in the OSHA assessment, EPA's 2014 assessment, and the Risk Evaluation and requested further explanation. *See, e.g.,* 2-NFEJ_ER-275. The Risk Evaluation and EPA's response to comments on the draft do not give that explanation.

EPA is required to publish responses to Science Committee comments, as well as public comments on draft risk evaluations and preliminary documents. 40 C.F.R. § 702.51(f), (g); *see also supra* Case Stmt. II & 2-NFEJ_ER-257. More generally, a fundamental principle of administrative law is that "[a]n agency must consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). A comment is "significant," and requires a response, if it "raise[s] relevant points and which, if adopted, would require a change in the agency's [proposal]." *Altera Corp. & Subsidiaries v. Comm'r of Internal Revenue*, 926 F.3d 1061, 1081 (9th Cir. 2019) (citation omitted), *cert. denied*, 141 S. Ct. 131 (2020).

The variations in the methylene chloride IURs described above are significant and warrant an explanation. Had EPA used the OSHA IUR it departed from, EPA would have found that methylene chloride poses an unreasonable risk to additional workers, including those exposed through processing the chemical as

a reactant. 1-NFEJ_ER-129–30; *supra* Case Stmt. III.A.2. While EPA need not use precisely the same figures as OSHA, the Science Committee and other comments seeking an explanation of the nearly thirtyfold difference between OSHA's IUR and the one EPA applied for most conditions of use "deserve[] an answer." *La. Fed. Land Bank Ass'n, FLCA v. Farm Credit Admin.*, 336 F.3d 1075, 1081 (D.C. Cir. 2003). EPA's failure to provide one renders its decision arbitrary and capricious.[40] *See Tesoro Alaska Petroleum Co. v. Fed. Energy Regul. Comm'n*, 234 F.3d 1286, 1294 (D.C. Cir. 2000) ("Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned.").

V. EPA violated TSCA and acted arbitrarily and without substantial evidence by failing to adequately account for the fact that people can be exposed to methylene chloride in more than one way

TSCA requires EPA to determine whether "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, or … *any combination of such activities*, presents an unreasonable risk," 15 U.S.C. § 2605(a) (emphasis added), and to "integrate and assess available information on hazards and exposures for the conditions of use … including information that is relevant to specific risks of injury to health," *id.* § 2605(b)(4)(F)(i). People who are exposed to methylene chloride typically absorb the chemical by breathing it and by touching

[40] If EPA's provision of an explanation prompts it to change the IUR numbers it used in the Risk Evaluation, it must update the corresponding risk determinations.

it. People may also be exposed to methylene chloride in more than one setting or context—for example, while at work, while breathing polluted air, and while using consumer products that contain the chemical. To develop a complete and accurate evaluation of methylene chloride's risks to human health, EPA had to account for these combined exposures. EPA did not.

A. EPA unlawfully failed to combine individuals' inhalation and dermal exposures, which occur simultaneously

Methylene chloride enters people's bodies through both inhalation and dermal contact, and both exposure routes contribute to health risks. 1-NFEJ_ER-171, 53; *see also* 40 C.F.R. § 702.33. EPA acknowledges that "[i]nhalation and dermal exposures … occur simultaneously" for exposed individuals. 1-NFEJ_ER-12; *see also* 1-NFEJ_ER-180. But EPA did not combine estimated inhalation and dermal exposures before determining unreasonable risk. Rather, "inhalation and dermal exposures were assessed separately" and compared separately to EPA's unreasonable-risk thresholds—an approach EPA concedes may have led it to underestimate actual exposures and risks. 1-NFEJ_ER-173.[41] In response to comments criticizing its approach, EPA summarily asserted that adding dermal and inhalation exposures would "result in an overestimate of risk," 2-NFEJ_ER-232, and "introduce additional uncertainties," 1-NFEJ_ER-180.

[41] *See also* 1-NFEJ_ER-129–54 (listing separate inhalation and dermal exposure estimates and comparing each to unreasonable-risk threshold).

The prospect of some uncertainty or overestimation is not an adequate reason for failing to combine inhalation and dermal exposures. TSCA recognizes that evaluating risks involves grappling with uncertainty, *see* 15 U.S.C. § 2625(h)(4), and the Risk Evaluation refers to many steps EPA took to assess exposures and health risks even though it was aware of some "uncertainty" that might lead it to over- or underestimate.[42] Assuming, *arguendo*, that EPA had to choose between over- and underestimation in order to combine dermal and inhalation exposures, overestimation furthers Congress's intent by ensuring that risk evaluations identify any unreasonable risk posed by chemicals and lead to risk-management rules that eliminate unreasonable risk. *See* 15 U.S.C. § 2605(a)(1); *supra* Case Stmt. II; *see also Pritzker*, 828 F.3d at 1135-40 (agency acted arbitrarily and violated mandate to achieve the least practicable adverse impact on marine mammals by resolving a data gap by erring on the side of underprotection).

EPA never says it would be impossible to either sum its inhalation and dermal-exposure estimates (or use some other method to account fully for those routes' combined contributions to health risks). Indeed, EPA aggregates exposures when assessing risks under other laws it administers. *See, e.g.*, 21 U.S.C. § 346a(b)(2)(A)(ii) (Food Quality Protection Act) (EPA may allow pesticide

[42] *See, e.g.*, 1-NFEJ_ER-50–51, 173–74, 175, 177.

residues on food if it finds "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information").

EPA's refusal to combine inhalation and dermal exposures led it to understate risks to everyone exposed to methylene chloride through both routes. This was arbitrary, unsupported by substantial evidence, and contrary to TSCA's "best available science" requirement. *See* 15 U.S.C. § 2625(h); *Turtle Island Restoration Network v. U.S. Dep't of Com.*, 878 F.3d 725, 739 (9th Cir. 2017) (agency acted arbitrarily and contrary to the ESA's best available science standard by refusing to incorporate information regarding risks it was "unable to quantify" but recognized "would be detrimental" into its analysis of whether increased fishing would jeopardize a species).

B. EPA unlawfully failed to account for the fact that many people will be exposed through more than one condition of use

EPA did not evaluate the combined risks to anyone who is exposed to methylene chloride through more than one condition of use. Rather, EPA analyzed each condition of use independently, as if there is no overlap among the groups of people exposed through each condition.[43] *See, e.g.*, 1-NFEJ_ER-129–42 (table

[43] TSCA directs EPA to determine whether "*a chemical substance* presents an unreasonable risk." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). Petitioners do not concede that EPA's use-by-use risk determinations satisfy that requirement.

presenting separate risk estimates for people exposed through each occupational condition of use); 2-NFEJ_ER-225–26 (public comment summary and response concerning EPA's failure to combine the risks presented by different conditions of use). EPA's risk determinations are accordingly predicated on an assumption that no person will be exposed to methylene chloride in more than one way.

This bears no relationship to reality. The record shows, and it was certainly reasonably foreseeable to EPA, that people may be exposed to methylene chloride through more than one of the fifty-three "activities," 15 U.S.C. § 2605(a), or "circumstances," *id.* § 2602(4), that EPA identified as the chemical's conditions of use. *See* 1-NFEJ_ER-198–201 (listing the conditions of use).

Take, for example, workers in the industrial facilities where methylene chloride is manufactured, processed as a reactant, recycled, and disposed of—activities EPA identified as conditions of use and determined present no unreasonable risk. *See* 1-NFEJ_ER-198–201. Because those facilities tend to release methylene chloride to the environment, EPA knew or could have foreseen that some workers will be exposed not only on the job, but also by breathing polluted air while commuting to work, and while living nearby.[44] EPA also knew

[44] *See supra* Case Stmt. I & Arg. I (discussing releases of methylene chloride to the environment from manufacturing and other facilities); 2-NFEJ_ER-225 ("EPA did not consider background exposure that workers and consumers using products containing [methylene chloride] might be exposed to in addition to exposures from

or could have foreseen that some of these workers would have hobbies or home-maintenance tasks that call for them to use products formulated with methylene chloride, such as hobby glues and automotive care products. *See* 1-NFEJ_ER-201. These are product classes that EPA found present an unreasonable risk even when considered independently, based on EPA's assumption that each would be the sole source of methylene chloride exposure for the people who use it. *See id.*

EPA did not contest public comments to the effect that "concurrent workplace, consumer product, and environmental exposures" are "common occurrences for many individuals and communities." 2-NFEJ_ER-225. Many people work in the industrial settings EPA classified as presenting no unreasonable risk, and there are consumer and commercial uses of methylene chloride that could serve as additional sources of exposure and risk to those individuals.[45]

EPA acknowledges that its failure to account for such combined exposures may have led to "underestimation of risk," 2-NFEJ_ER-225, including for the tens of thousands of workers exposed through the six conditions of use EPA found do

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TSCA-regulated conditions of use"); *see also infra* Arg. VI. & NFEJ-PA-56–66 (¶¶ 2-8 & Exs. 1-2) (evidence of releases from facilities near Petitioners' members' homes).

[45] *See* 2-NFEJ_ER-273 (public comment explaining that workers exposed in one of the occupational settings EPA analyzed may also be exposed through consumer products they or family members use at home); 2-NFEJ_ER-262–63 (Science Committee comment explaining that methylene chloride can be present in homes' indoor air and water supplies, as well as in consumer products used and stored in homes); *supra* Case Stmt. III & n.8 (worker counts).

not present an unreasonable risk when considered independently.[46] The only reason EPA gives for failing to combine exposures that stem from different conditions of use is the one it gave for excluding environmental releases. *Compare* 2-NFEJ_ER-225–26, *with supra* Arg. I. That rationale is unlawful for the reasons already discussed. *See supra* Arg. I, Arg. V.A. It is also wholly unresponsive to comments about EPA's failure to combine exposures that stem from methylene chloride's use in different interior settings, such as plants where the chemical is made and homes and commercial spaces where people use products that contain the chemical.

* * * *

The Risk Evaluation and EPA's determinations that six occupational conditions of use do not present an unreasonable risk to workers are unlawful for the reasons set forth above. To ensure that the public receives the level of information about and protection from methylene chloride that Congress mandated in its 2016 amendments to TSCA, this Court should vacate EPA's six no-unreasonable-risk determinations and order EPA to revise the Evaluation to correct the errors and omissions identified in Arguments I through V above.

[46] 1-NFEJ_ER-173 ("[E]xposures to methylene chloride from outside the workplaces are not included in the occupational assessment, which may lead to an underestimate of occupational exposure").

VI. Petitioners have standing to challenge the Risk Evaluation

Petitioners have standing to challenge the Risk Evaluation under the three-part test for associational standing established in *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333, 343 (1977). First, the interests Petitioners seek to protect in this case are germane to their organizational purposes. *See id.* They are not-for-profit labor, environmental, and public-health advocacy groups who work to protect their members from exposures to toxic chemicals including methylene chloride and educate their members about those chemicals.[47]

Second, this Court can adjudicate the legal issues presented and grant the relief requested in this brief without the participation of individual members of Petitioners. *See Hunt*, 432 U.S. at 342-43.

Third, as explained below, Petitioners' members would have standing to sue on their own behalf. *Id.* They are injured by the violations discussed in this brief, and their injuries are traceable to EPA's failure to prepare a lawful and comprehensive risk evaluation and redressable through the relief Petitioners request. *See Or. Nat. Desert Ass'n v. Dombeck*, 172 F.3d 1092, 1094-95 (9th Cir. 1998) (applying the three-part test for Article III standing).

[47] NFEJ_PA-6 (¶¶ 1-2); NFEJ_PA-13–14 (¶ 4); NFEJ_PA-18–20 (¶¶ 1, 3, 6-7); NFEJ_PA-35–36 (¶¶ 4, 6); NFEJ_PA-40–42 (¶¶ 4-5, 8); NFEJ_PA-68–70 (¶¶ 3-10).

A. Petitioners' members are injured by EPA's violations

EPA's violations have exposed Petitioners' members to a "credible threat of real and immediate harm" (and a "substantial risk" of harm). *See In re Zappos.com, Inc.*, 888 F.3d 1020, 1026-27 (9th Cir. 2018) (describing requirements for Article III standing). The members of Petitioners United Steelworkers and New Jersey Work Environment Council (NJWEC) include people who are exposed to methylene chloride through several of the occupational conditions of use—working in manufacturing, processing, and disposal facilities—that EPA found do not present an unreasonable risk. NFEJ_PA-41 (¶ 6); NFEJ_PA-21 (¶¶ 9-10).

Petitioners Neighbors for Environmental Justice, Sierra Club, and NRDC have members who live near industrial facilities that emit methylene chloride in association with conditions of use EPA found present no unreasonable risk to workers (such as facilities that recycle and/or dispose of the chemical).[48] These members breathe air that is polluted with the chemical and are concerned about the chemical's threats to their health, economic, recreational, and aesthetic interests and the well-being of their families and communities.[49]

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[48] NFEJ_PA-56–60 (¶¶ 2-8), 64, 66.

[49] NFEJ_PA-6–10 (¶¶ 1-2, 4-11); NFEJ_PA-13–17 (¶¶ 2, 5-15); NFEJ_PA-24–29 (¶¶ 2-16); NFEJ_PA-31–34 (¶¶ 1, 4-14); NFEJ_PA-47–51 (¶¶ 2-16); NFEJ_PA-53–55 (¶¶ 2-10); NFEJ_PA-56–61 (¶¶ 2-8), 64, 66.

Members of these groups, like members of the United Steelworkers and NJWEC, are injured by EPA's exclusion of environmental releases, exposures, and risks; failure to identify neighboring communities as a potentially exposed subpopulation and assess risks to that subpopulation; failure to assess risks to the subpopulation that is more genetically susceptible to methylene chloride; and failures to account for combined exposures. *See Safer Chems.*, 943 F.3d at 418, 421-22 (groups including some Petitioners had standing to challenge TSCA regulations they feared would lead EPA to "understate risks associated with chemicals … evaluated" and "exclude[] necessary information from EPA's publications," based on evidence that their members would be exposed to chemicals in settings and through uses the regulations purported to allow EPA to exclude from its analysis); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001) (credible threats of harm to one's physical well-being or aesthetic or recreational satisfaction constitute injury); *supra* Case Stmt. I (surveying health risks associated with methylene chloride exposure).

B. Petitioners' members' injuries are traceable to EPA's violations and redressable through a favorable ruling

Petitioners seek to enforce a review and regulatory process mandated by TSCA, "the disregard of which could impair" their members' concrete interests in minimizing exposure to a dangerous chemical. *See Dombeck*, 172 F.3d at 1094 (quoting *Lujan v. Defs. of Wildlife,* 504 U.S. 555, 572 (1992)). This case

accordingly concerns procedural violations, *see id.*, and the normal redressability and traceability requirements are "relaxed." *Cottonwood Env't L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1083 (9th Cir. 2015); *see also Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1355 & n.14 (9th Cir. 1994) (plaintiffs established causation and redressability where agency's inadequate analysis could cause environmental and health consequences to be overlooked).

Petitioners' members' injuries are traceable to EPA's procedural violations. The errors and omissions Petitioners have identified led EPA to ignore or understate risks to everyone exposed to the environmental releases EPA excluded, including residents of communities around industrial and commercial methylene chloride emitters and those with special genetic susceptibility. They also led EPA to understate risks to everyone through the occupational conditions of use EPA found present no unreasonable risk, as well as everyone exposed through more than one of the exposure routes, activities, or other circumstances EPA treated as distinct for purposes of its risk determinations. *See generally supra* Args. I-V. Petitioners have members in all of these ignored and underprotected groups.

The revised and expanded risk evaluation Petitioners seek would help to redress their members' injuries. It would account for the full range of methylene chloride releases and exposures that presently threaten Petitioners' members' health, economic, and other interests, and would almost certainly lead EPA to

identify additional sources of unreasonable risk (which TSCA requires EPA to eliminate through risk management, *supra* Case Stmt. II).[50] Even if it did not lead to additional regulation of methylene chloride, a revised and expanded evaluation would provide more information about methylene chloride's conditions of use and threats to health and the environment that Petitioners' members and staff could use to better inform and protect themselves and others.[51] *See Friends of Animals v. Jewell*, 824 F.3d 1033, 1040-41 (9th Cir. 2006) (a denial of access to information constitutes injury for standing purposes, at least where a law requires disclosure and there is no reason to doubt that the information would help the claimant).

Petitioners have standing.

CONCLUSION

The Court should vacate EPA's six no-unreasonable-risk determinations for methylene chloride and direct EPA to revise the Risk Evaluation to correct the errors and omissions discussed in this brief.

Respectfully submitted January 25, 2021,

s/Selena Kyle
SELENA KYLE
Natural Resources Defense Council
1600 N. Wacker Dr., Ste. 1600

s/Jonathan Kalmuss-Katz
JONATHAN KALMUSS-KATZ
Earthjustice
48 Wall St., 15th Fl.

[50] *See* 15 U.S.C. § 2605(a); NFEJ_PA-10 (¶ 12); NFEJ_PA-16–17 (¶¶ 15-16); NFEJ_PA-22 (¶ 13); NFEJ_PA-28–29 (¶¶ 15-16); NFEJ_PA-33–23 (¶¶ 13-14); NFEJ_PA-42–43 (¶ 10); NFEJ_PA-51 (¶ 17); NFEJ_PA-54–55 (¶¶ 9-10).

[51] *See* NFEJ_PA-18–20 (¶¶ 3, 6-7); NFEJ_PA-42–43 (¶¶ 9-10); NFEJ_PA-6 (¶ 1); NFEJ_PA-69–70 (¶¶ 6-10); NFEJ_PA-36–37 (¶ 8).

Chicago, IL 60606
T: 818.720.5953
skyle@nrdc.org

ROBERT GUSTAFSON
Natural Resources Defense Council
40 W. 20th St., Fl. 11
T: 847.977.8339
rgustafson@nrdc.org

Attorneys for Petitioners Neighbors for Environmental Justice and Natural Resources Defense Council

s/Randy S. Rabinowitz
RANDY S. RABINOWITZ
Occupational Safety & Health Law Project
P.O. Box 3769
Washington, DC 20027
T: 202.256.4080
randy@oshlaw.org

Attorney for Petitioner United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO

New York, NY 10005
T: 212.845.7376
jkalmusskatz@earthjustice.org

Attorney for Petitioners Neighbors for Environmental Justice, New Jersey Work Environment Council, and Sierra Club

STATEMENT OF RELATED CASES

Petitioners identify the consolidated cases Alaska Community Action on Toxics v. EPA (9th Cir. Case No. 20-73099), California Professional Firefighters et al. v. EPA (9th Cir. Case No. 20-73578), and International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW v. EPA (9th Cir. Case No. 21-70009) as related. These three cases challenge EPA's final risk evaluation for hexabromocyclododecane under TSCA, concern many of the same TSCA provisions Petitioners seek to enforce in this case, and accordingly "raise … closely related issues." 9th Cir. R. 28-2.6(b).

Dated: January 25, 2021

/s/Selena Kyle
SELENA KYLE
Natural Resources Defense Council
1600 N. Wacker Dr., Ste. 1600
Chicago, IL 60606
T: 818.720.5953
skyle@nrdc.org

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This brief complies with the type-volume limitation of Ninth Circuit Rules 32-1(a) and 32-2(b) because it contains 15,394 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word and 14-point Times New Roman font.

Dated: January 25, 2021

/s/Selena Kyle
SELENA KYLE
Natural Resources Defense Council
1600 N. Wacker Dr., Ste. 1600
Chicago, IL 60606
T: 818.720.5953
skyle@nrdc.org

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Dated: January 25, 2021

/s/Selena Kyle
SELENA KYLE
Natural Resources Defense Council
1600 N. Wacker Dr., Ste. 1600
Chicago, IL 60606
T: 818.720.5953
skyle@nrdc.org

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